

REMARKS/ARGUMENTS

Applicant respectfully requests reconsideration of the present case in view of the above amendments and the following remarks.

Claims 1-13 are currently pending. Claims 1-13 are rejected. Claims 1-11 have been cancelled. Claims 12 and 13 have been amended. Claims 14-23 have been added. No new matter has been inserted.

Support for the amendments to claim 12 and 13 can be found throughout the specification as filed, including at least in paragraph 21. The amendments to claim 12 and 13 were merely for grammatical and typographical corrections.

Support for the newly added claims (14-23) dependent to claim 12 can be found throughout the specification as filed, including at least in paragraph 46 and in claims 2-11 as originally filed.

Claim Objections

The Examiner objected to the disclosure because of the following informalities: The word – fibers – in claim 1 is misspelled as “fibres”, also – fiber – in claim 3-7 is misspelled as “fibre”. Without acquiescing to the objection and solely for the purpose of advancing prosecution, claims 1 and 3-7 have been cancelled thereby making this objection moot. Withdrawal of the objection is respectfully requested.

Claim Rejections

Under 35 U.S.C. §112

The Examiner rejected Claim 3 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses the rejection.

Without acquiescing to the rejection and solely for the purpose of advancing prosecution, claim 3 has been cancelled making this rejection moot. Withdrawal of the rejection is respectfully requested.

Under 35 U.S.C. § 101

Claims 1-13 are rejected under 35 U.S.C. § 101, because the claimed invention is directed to non-statutory subject matter for being directed to the formulation of naturally occurring bacteria. Applicant respectfully traverses the rejection.

Without acquiescing to the rejection and solely for the purpose of advancing prosecution, claims 1-11 have been canceled making the rejection with regards to these claims moot.

Claims 12-23 are directed to a method for preventing and/or treating a stress induced inflammatory disease and are not directed to a formulation for producing naturally occurring bacteria. Therefore, a rejection to these claims for being directed to a method of formulation is unsupported. Claims 12-23 do not prevent any substantial practical application of a product of nature. Therefore, claims 12-23 are directed to statutory subject matter and should be allowed. Withdrawal of the rejection is respectfully requested.

Under 35 U.S.C. § 103(a)

Claims 1-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Monte (US 2003/0147857 A1) in view of Kruszewskya et al. (in IDS, Microecology and Therapy, 2002, Vol. 29, p.37-49) and further in view of Kaur et al. (European Journal of Pharmaceutical Sciences, 2002, Vol. 15, p.1-9 and further in view of Bengs et al. (U.S. Patent No. 7,097,831 B1) and further in view of Zhang et al (JBC, 2002, Vol. 277, p.46116-46122). Applicant respectfully traverses the rejection.

Claims 12-23 are not obvious because the cited references do not teach or suggest that each of the specific bacterial strains (*Pediococcus pentosaceus* 16:1 (LMG P-20608), *Leuconostoc mesenteriodes* 23-77:1 (LMG P-20607), *Lactobacillus paracasei subsp paracasei* F-19 (LMG P-17086), and *Lactobacillus plantarum* 2362 (LMG P-20606)) should be utilized in an amount of at least 10^{11} CFU/ml, that all four specific bacterial strains should be combined and utilized with at least four fibers, or that this formulation can be utilized to prevent and/or treat a stress-induced inflammatory disorder in a mammal as claimed in the Instant Application. Further, Kruszewskya et al. teaches away from preventing and/or treating a stress-induced inflammatory disorder in a mammal as claimed in the Instant Application.

The Patent Office asserts that Monte teaches a formulation for a probiotic including *Pediococcus pentosaceus*, *Lactobacillus paracasei*, and *Lactobacillus plantarum*, wherein each of the bacterial strains are in an amount of 10^{10} or more, and a prebiotic including beta glucan, inulin, pectins, and vitamins to treat a mammal. (Office Action, p. 4-5).

However, Monte recites, "There is no published standard that should be in a probiotic product or dosage, only estimated figures ranging from 10^6 to 10^{10} bacteria per day, depending on the conditions of the host." (Monte, para. 28). The dosage of 10^6 to 10^{10} **bacteria per day** depending upon the condition of the host as disclosed in Monte does not teach or suggest a dosage of at least 10^{11} **CFU/ml** (Colony forming unit per milliliter) as claimed in the Instant Application. Neither Kruszewskya et al., Kaur et al., Bengs et al., or Zhang et al. teach nor suggest the claimed dosage. Therefore, the claims of the Instant Application cannot be obvious over Monte in view of Kruszewskya et al., Kaur et al., Bengs et al., and Zhang et al.

The Patent Office concedes that Monte does not teach or suggest the utilization of *Leuconostoc mesenteriodes* 23-77:1 (LMG P-2067), *L. Paracasei subsp paracasei* F-19 (LMG P-17086), or *L. plantarum* 2362 (LMG P-20606). (Office Action, p. 5). Additionally, Monte does not teach or suggest the specific strain (16:1 (LMP P-20608) of the *Pediococcus pentosaceus* 16:1 (LMP P-20608) as claimed in the Instant Application.

Monte does list some unspecific strains of the claimed invention in a laundry list with numerous other unspecific strains and discloses that one or more of these probiotics could be utilized to form the prebiotic and probiotic composition. (Monte, para. 25). However, Monte does not recite the specific bacterial strains or the specific combination of these four strains as claimed in the Instant Application. Further, Monte does not recite the specific combination of these four strains with at least four fibers as claimed in the Instant Application. Instead, Monte lists a number of the fibers in a laundry list of numerous prebiotics and discloses that one or more of these prebiotics could be utilized to form the prebiotic and probiotic composition. Therefore, the formulation comprising one or more of the laundry list of possible probiotics in combination with one or more of the laundry list of possible prebiotics as disclosed in Monte does not teach or suggest the formulation comprising four specific strains and at least four fibers as claimed in the Instant Application. None of the cited references teach or suggest a

formulation comprising four specific bacterial strains and at least four fibers as claimed in the Instant Application. Thus, the claims of the Instant Application cannot be obvious over Monte in view of Kruszewskya et al., Kaur et al., Bengs et al., and Zhang et al.

Moreover, Monte does not recite that the prebiotic and probiotic formulation can be utilized to prevent and/or treat a stress-induced inflammatory disorder in a mammal as claimed by the Instant Application. Monte discloses that the prebiotic and probiotic composition is utilized to benefit mammalian health and in particular gastrointestinal health. (Monte, para. 25). The disclosure of general health benefits does not teach or suggest a specific treatment for a specified disease. Therefore, the prebiotic and probiotic composition's benefit to mammalian health and in particular gastrointestinal health as disclosed in Monte does not teach or suggest a composition that can be utilized to prevent and/or treat a stress-induced inflammatory disorder in a mammal as claimed in the Instant Application. Neither Kruszewskya et al., Kaur et al., Bengs et al., nor Zhang et al. teach or suggest a composition that can be utilized to prevent or treat a stress-induced inflammatory disorder in a mammal as claimed in the Instant Application. Thus, the claims of the Instant Application cannot be obvious over Monte in view of Kruszewskya et al., Kaur et al., Bengs et al., and Zhang et al.

The Patent Office asserts that Kruszewskya et al. teaches the *Pediococcus pentosaceus* 16:1 (LMG P-20608), *Leuconostoc mesenteroides* 23-77:1 (LMG P-2067), *L. paracasei subsp paracasei* F-19 (LMG P-17086), or *L. plantarum* 2362 (LMG P-20606), or the specific strains not disclosed in Monte, and that these strains have anti-inflammatory properties. (Office Action, p. 5).

However, Kruszewskya et al. discloses the *L. plantarum* 2592 strain and not the *L. plantarum* 2362 strain as claimed in the Instant Application. The *L. plantarum* 2592 strain disclosed in Kruszewskya et al. does not teach or suggest the *L. plantarum* 2362 strain as claimed in the Instant Application. No other cited reference discloses the *L. plantarum* 2362 strain as claimed in the Instant Application. Therefore, the claims of the Instant Application cannot be obvious over Monte in view of Kruszewskya et al., Kaur et al., Bengs et al., and Zhang et al.

Further, Kruszewskya et al. tested each of the listed strains above and several others individually to determine their characteristics. (Kruszewskya et al., p. 43). Kruszewskya et al. does not teach or suggest utilizing any of these strains in combination or with at least four fibers. Therefore, the individual strain and their determined properties as disclosed in Kruszewskya et al. do not teach and suggest the formulation of four specific bacterial strains with at least four fibers as claimed in the Instant Application. None of other cited references disclose the formulation of four specific bacterial strains with at least four fibers as claimed in the Instant Application. Thus, the claims of the Instant Application cannot be obvious over Monte in view of Kruszewskya et al., Kaur et al., Bengs et al., and Zhang et al.

Further, Kruszewskya et al. does not teach or suggest that these strains can be utilized to prevent and/or treat a stress-induced inflammatory disorder in a mammal as claimed by the Instant Application. Kruszewskya et al. recites that: "there is an increasing interest to add selected strain to food items to prevent or treat various diseases, such as infectious, allergy, inflammatory bowel disease, and cancer." However, Kruszewskya et al. concludes that these commercial products have been based on insufficient in vitro and in vivo data. (Kruszewskya et al. p. 43). Kruszewskya et al. further concludes that its own tests do not conclusively show if these strains are effective to treat any specific diseases. (Kruszewskya et al. p. 45). Therefore, the inconclusive results of the Kruszewskya et al. do not teach or suggest that any of these strains individually could be utilized to treat a specific disease, let alone that any of these strains formulated in a specific combination with at least four fibers could be utilized to treat or prevent a stress-induced inflammatory disorder in a mammal as claimed in the Instant Application. None of the cited references disclose that the formulation of the specific bacterial strains combined with at least four fibers to prevent and/or treat a stress-induced inflammatory disorder in a mammal as claimed in the Instant Application. Thus, the claims of the Instant Application cannot be obvious over Monte in view of Kruszewskya et al., Kaur et al., Bengs et al., and Zhang et al.

Further, none of the individual bacterial strain tests performed in Kruszewskya et al. demonstrate that any of the claimed strains have an anti-inflammatory effect except for *L. paracasei subsp paracasei* F-19, which was shown to have an anti-inflammatory effect (the

production of IL-10). (Kruszewskya et al. Fig. 3, Table 3, and page 45). However, the tests in Kruszewskya et al. also showed that *Paracasei subsp paracasei* F-19 has a pro-inflammatory effect (the production of IL-8). (Kruszewskya et al. Fig. 3, Table 3, and page 45). When compared, the *Paracasei subsp paracasei* F-19 induced a larger amount of the pro-inflammatory IL-8 than the anti-inflammatory IL-10. (Kruszewskya et al. Fig. 3, Table 3, and page 45). Therefore, the specific tests disclosed in Kruszewskya et al. teach and suggest that *Paracasei subsp paracasei* F-19 probably has a pro-inflammatory effect. The suggested pro-inflammatory effect of *Paracasei subsp paracasei* F-19 disclosed in Kruszewskya et al. teaches directly away from the method for preventing and treating a stress-induced inflammatory disorder in a mammal as claimed by the Instant Application. None of the other cited references teach or suggest a formulation that can be utilized in a method to prevent and/or treat a stress-induced inflammatory disorder in a mammal as claimed in the Instant Application. Thus, the claims of the Instant Application cannot be obvious over Monte in view of Kruszewskya et al., Kaur et al., Bengs et al., and Zhang et al.

The Office Action has failed to establish that the cited references teach or suggest the claims of the Instant Application. Accordingly, in view of the forgoing differences, Applicants respectfully submit the Office Action has failed to establish a *prima facie* case of obviousness. Withdrawal of the rejections is respectfully requested.

REQUEST FOR RECONSIDERATION

In view of the foregoing amendments and remarks, all pending claims are believed to be allowable and the application is in condition for allowance. Therefore, a Notice of Allowance is respectfully requested. If the Examiner believes a telephone conference would advance the prosecution of this application or if the Examiner should have any further issues regarding this application, the Examiner is invited to contact the undersigned attorney for the applicant at the telephone number provided below.

Respectfully submitted,

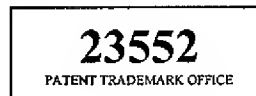
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